

Oral Argument Scheduled for March 21, 2025

NO. 24-1151

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

**UNITED STEEL, PAPER AND FORESTRY, RUBBER,
MANUFACTURING, ENERGY, ALLIED INDUSTRIAL AND SERVICE
WORKERS INTERNATIONAL UNION, AFL-CIO,**

Petitioner,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY,

Respondent.

CONSOLIDATED WITH CASES
Nos. 24-1182, 24-1185, 24-1202, 24-1237

**REPLY BRIEF OF PETITIONERS UNITED STEELWORKERS,
INTERNATIONAL ASSOCIATION OF MACHINISTS AND
WORKSAFE, INC.**

Randy S. Rabinowitz
Victoria L. Bor
Occupational Safety and Health Law
Project, LLC
P.O. Box 3769
Washington, D.C. 20027

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INTRODUCTION

These Petitions challenge the validity of the determination of the Environmental Protection Agency (“EPA” or “the Agency”) to vest itself with discretion to consider the use of personal protective equipment (“PPE”) in conducting its science-based risk evaluations under the Toxic Substance Control Act (“TSCA”), a determination Congress directed the Agency to make using “the best available science” and without consideration of “costs and other nonrisk factors.” For over 40 years, while “little to no action to regulate existing chemicals under TSCA occurred,” Brief of Respondent EPA (“EPA Br.”) 7, the two Federal agencies singularly focused on workplace safety and health, the Occupational Safety and Health Administration (“OSHA”) and the National Institute of Occupational Safety and Health (“NIOSH”), have forged a well-settled approach to occupational exposure assessment – an integral component of evaluating the risks chemicals pose in the workplace. This approach is based on core principles of industrial hygiene and has been upheld when challenged. EPA has nonetheless promulgated a regulation in its “Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act,” 89 Fed. Reg. 37028 (May 3, 2024), that would grant the Agency uncabined discretion to reduce measured exposures to a toxin by the supposed “efficacy” of PPE, such as respirators. The United Steelworkers, International Association of Machinists, and Worksafe, Inc.

(the “Labor Petitioners”) ask this Court to strike the first sentence of the PPE Rule, 40 C.F.R. § 702.39(f)(2), because it upends that settled approach to assessing occupational exposures.¹

Before responding to EPA’s arguments, the Labor Petitioners want to make clear what is at stake. Since Congress passed the Occupational Safety and Health Act (“OSH Act”) over 50 years ago, OSHA and NIOSH have gauged worker exposure without regard to PPE for purposes of both evaluating and managing the risks associated with workplace exposure to hazardous substances. EPA’s stated intent in the PPE Rule to take “reasonably available information” on “*actual* use and efficacy” of respirators into account in determining whether a chemical presents an unreasonable risk to workers would effectively upend this long-standing and universally accepted approach. And it would undermine Congress’ intent that EPA determine whether exposure to a particular toxic substance poses “unreasonable risks,” by reducing measurements of “employee exposure” by some measure of respirator “efficacy.”

EPA has not cited a single example of when this technique has previously been used. It has offered no examples of the type or quantum of data that would persuade it that respirators are used, nor explained how it will assess PPE’s

¹ In this brief, references to the entire regulation will be to “the Framework Rule;” references to the provision implicated here – 40 C.F.R. § 702.39(f)(2) – will be to “the PPE Rule.”

efficacy. It cites no academic literature to support its stated intent to consider only a fraction of reported exposures when assessing risk. Moreover, both OSHA and NIOSH told EPA this approach is wrong.

It is universally understood that PPE is the least effective and least reliable means of controlling workplace exposure.² Basic principles of industrial hygiene, OSHA regulations, and even EPA's risk management rules require employers to determine workplace exposure without regard to respirators. EPA's assertion of the right to ignore this fundamental industrial hygiene principle violates TSCA because the use of PPE is a "nonrisk factor," consideration of which the Statute explicitly prohibits, and which flies in the face of the "best available science." By claiming the right to do so, EPA is acting irrationally and contrary to law.

² For example, a recurring issue underlying disputes about the reasonableness of OSHA health standards has been whether OSHA should permit routine reliance on respirators as a tool to protect workers from exposure rather than insisting on more expensive, but more effective, engineering or work practice controls. *See AFL-CIO v. Marshall*, 617 F.2d 636, 652–55 (D.C. Cir. 1979) (cotton dust); *United Steelworkers v. Marshall*, 647 F.2d 1189, 1269 (D.C. Cir. 1980); *ASARCO v. OSHA*, 746 F.2d 483, 497 (9th Cir. 1984); *Am. Iron & Steel Inst. v. OSHA*, 182 F.3d 1261 (11th Cir. 1999). This Court has unequivocally endorsed OSHA's preference for engineering solutions to hazardous workplace exposures. *AFL-CIO v. Marshall*, *supra* (approving reliance on engineering controls over urine measurements coupled with respirator use); *United Steelworkers*, *supra* (approving reliance on engineering controls over blood lead measurements coupled with respirator use).

ARGUMENT

I. Standard of Review

EPA is correct that, pursuant to 15 U.S.C. § 2618(c)(1)(B), the Administrative Procedure Act (“APA”) provides the appropriate standard of review. EPA Br. 17. Under the APA, this Court is to “set aside agency action” that is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A). “Most fundamentally, the APA’s arbitrary-and-capricious standard requires that agency action be reasonable and reasonably explained.” *Huntsman Petrochem., LLC v. EPA*, 114 F.4th 727, 735 (D.C. Cir. 2024) (internal quotations and citation omitted).

Under this standard, EPA’s assertion that it can take PPE into account in conducting its risk evaluations is arbitrary and capricious because it “relie[s] on factors which Congress has not intended it to consider, entirely fail[s] to consider an important aspect of the problem, offered an explanation of its decision that runs counter to the evidence before [it], and is so implausible that it [cannot] be ascribed to a difference in view or the product of agency expertise.” *Baystate Franklin Med. Ctr. v. Azur*, 950 F.3d 84, 89 (D.C. Cir. 2020) (quoting *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)).

II. EPA Has Not Explained the Text of the PPE Rule

The text of the PPE Rule reads as follows:

In determining whether unreasonable risk is presented, EPA's consideration of occupational scenarios will take into account reasonably available information, including known and reasonably foreseeable circumstances where subpopulations of workers are exposed *due to the absence or ineffective use of personal protective equipment*. EPA will not consider exposure reduction based on assumed use of personal protective equipment as part of the risk determination.

40 C.F.R. § 702.39(f)(2)(emphasis added). Labor Petitioners fully agree EPA should not *assume* PPE use in determining whether a toxic substance poses an unreasonable risk and therefore join EPA in opposing the Industry Petitioners' challenge to that policy.³ However, as Labor Petitioners explained in our opening

³ In support of their contention that EPA must assume PPE use, the Industry Petitioners assert that Congress did not intend TSCA to be a “worker protection law” and that TSCA § 9(a), 15 U.S.C. § 2608(a), requires EPA to refer worker safety regulation to OSHA whenever that agency “may” be able to address unreasonable risks. Brief of Texas Chemistry Council, et al., at 44–46. The Industry Petitioners are wrong on both points. First, in the 2016 amendments, Congress made clear EPA's responsibility to address workplace hazards by adding workers to the list of “potentially susceptible subpopulation” whose exposures EPA was to consider in conducting its risk evaluation and risk management obligations. 15 U.S.C. § 2602(12). Second, § 9(a), by its terms, provides EPA with discretion to refer regulation if, and *only* if, after conducting its risk evaluation, the EPA finds that: (1) another agency may take action to address the “unreasonable risk” EPA identified; (2) such action would “prevent[] or reduce[]” the risk; and (3) it would do so “to a sufficient extent,” considering TSCA's mandate that it regulate chemicals to ensure they “no longer present[] such risk.” *Id.* § 2605(a). This is a far higher bar, and provides EPA with far more discretion, than the Industry Petitioners suggest.

brief, the only way to make sense of the first sentence of this provision is that although the Agency will not assume that respirators are being used *effectively* in evaluating risk, it will take into account whether they are *not* being used or are being used *ineffectively*. On its face, this language presupposes that respirators are routinely provided to workers at all levels of exposure and that exposure occurs only when PPE is not provided or when it fails. In our opening brief, Labor Petitioners explained that OSHA imposes no such duty and EPA has identified none. Brief of Labor Petitioners (“Labor Br.”) 28-33.

In response, EPA asserts that the Labor Petitioners are mistaken in reading this provision to rest on an assumption that OSHA universally requires employers to provide respirators to protect their employees from workplace exposures. EPA Br. at 69–70. The Agency instead insists that this provision “merely provides that EPA will consider reasonably available information about [PPE] when conducting risk evaluations, and prohibits EPA, when determining risk, from *assuming* that workers will always and effectively use personal protective equipment.” *Id.* at 70. But that explanation does not engage with the PPE Rule’s actual language, for it fails to explain how the Agency will take exposures due to the “absence or ineffective use” of PPE into account if it is not starting from an understanding that PPE has been provided.

In any event, even if this provision could fairly be read simply to say that EPA will consider information on the effectiveness of PPE when it is provided, as we demonstrated in our opening brief and explain below, it is nonetheless contrary to TSCA's directive.

III. Considering PPE in Conducting a Risk Assessment Violates TSCA's Charge that EPA Use the Best Available Science

Congress intended EPA's risk determination to be a "science-based risk decision about a chemical's safety under its intended conditions of use." S. Rep. No. 114-67 (2015), AR Ex. 422 at 17 (Congress intended to "decouple" the risk determination "from [EPA's] decision on how to manage unreasonable risks"). As EPA itself explained in the preamble to the Framework Rule, "TSCA risk evaluations are subject to statutory science standards, an explicit requirement to consider risks to potentially exposed or susceptible subpopulations, and a prohibition on considering costs and other non-risk factors when determining whether a chemical presents an unreasonable risk that warrants regulatory actions." Framework Rule, 89 Fed. Reg. at 37037. TSCA directs EPA, in conducting its risk evaluation, to "describe the weight of scientific evidence" underlying the hazards and exposures it identifies. 15 U.S.C. § 2605(b)(4)(F)(iii), (v).

EPA acknowledges that "TSCA's science standards require [it] to weigh the scientific evidence" in conducting risk evaluations, citing 15 U.S.C. § 2625(i). EPA Br. 66. The Agency argues, however, that this requirement "does not negate

EPA's obligation to consider reasonably available information on workers' exposures," under 15 U.S.C. § 2625(k). *Id.* In making this argument, EPA is focusing on a "single sentence [in § 2625] . . . but [failing to] look to the provision[]" as a whole. *Carlson v. Postal Regulatory Comm'n*, 938 F.3d 337, 349 (D.C. Cir. 2019) ("[I]n expounding a statute, we must not be guided by a single sentence . . . but look to the provisions of the whole law.") (internal citations omitted).

Section 2625 broadly addresses EPA's responsibilities in administering TSCA. EPA is hanging its entire argument on subsection (k).⁴ While that subsection instructs the Agency to consider "reasonably available" information, subsection (i) directs EPA to base decisions regarding unreasonable risk on the weight of scientific evidence,⁵ and subsection (h) spells out the "statutory science

⁴ Section 2625(k) states that "[i]n carrying out section[] . . . 2605 of this title, the Administrator shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information under the conditions of use, that is reasonably available to the Administrator." 15 U.S.C. § 2625(k). This subsection does not require EPA to credit anything and everything submitted to it in its risk evaluation. Instead, the subsection should be interpreted to permit EPA to rely on *available* information in making predictions about the health effects of a chemical when the scientific evidence does not provide conclusive information on causation. *Cf. United Steelworkers v. Marshall*, 647 F.2d at 1266 (interpreting the phrase "best available evidence" in the OSH Act to mean that OSHA cannot let workers suffer while it awaits "the Godot of scientific certainty.")

⁵ "The Administrator shall make decisions under section[] . . . 2605 of this title based on the weight of the scientific evidence." 15 U.S.C. § 2625(i).

standards” EPA is to apply in evaluating “reasonably available” *scientific* information. Those standards include using the information in a manner that is “relevant” to EPA’s decision and “consistent with the intended use of the information” and “the best available science.” 15 U.S.C. § 2625(h)(1), (2). EPA must also take account of “the degree of clarity and completeness with which the data . . . are documented.” *Id.* § 2625(h)(3).

As the Labor Petitioners demonstrated in our opening brief, the “best available science” on evaluating exposure is represented by OSHA and NIOSH practice, which incorporates recognized industrial hygiene principles. As those agencies both told EPA, they do not take respirator use into account when assessing risk. AR Ex. 218 at Att 1-6. This is because it is not possible to take exposure measurements inside a respirator without breaking the seal that ensures the PPE’s effectiveness. Moreover, because of the number of variables that contribute to a respirator’s effectiveness—including its fit, cleanliness and maintenance and the employee’s training—it is impossible to generalize from the experience of a few workers to an entire cohort. Thus, information regarding PPE use is not “relevant” or “intended” to be used in assessing the employee exposure, and thus is not the “best available science” for assessing the risks pose by occupational exposure to a toxic chemical.

EPA's reasons for ignoring the views of the two expert agencies with experience evaluating employee exposure and occupational risk do not withstand scrutiny. First, EPA suggests it reasonably ignored OSHA and NIOSH's established risk evaluation practices because both agencies operate under a statute, the OSH Act, that differs from TSCA. EPA Br. 80–81. But nothing in the OSH Act or OSHA policies with respect to risk evaluation differ from TSCA's requirements. Since the *Benzene* decision, OSHA has been required to show a “significant risk in the workplace” before regulating, *Industrial Union Dep't v. Am. Petroleum Inst.*, 448 U.S. 607, 655–56 (1980) (“*Benzene*”); TSCA requires EPA to determine whether an “unreasonable risk” exists before regulating. Both inquiries require an exposure assessment. The differences between the two statutes to which EPA routinely points—OSHA's inability to ban a chemical, the OSH Act's prohibition on standards that are infeasible, its failure to protect public sector and self-employed workers⁶—are relevant to how OSHA manages risk, *not* to its risk

⁶ See, e.g., EPA, “Asbestos Part 1; Chrysotile Asbestos; Regulation of Certain Conditions of Use Under [TSCA],” 89 Fed. Reg. 21970, 21999 (Mar. 28, 2024); EPA, “Methylene Chloride; Regulation Under [(TSCA)],” 89 Fed. Reg. 39254, 39287 (May 8, 2024); EPA, “Trichloroethylene (TCE); Regulation Under [TSCA],” 89 Fed. Reg. 102568, 102616 (Dec. 17, 2024).

evaluation.⁷ They provide EPA with no basis for ignoring OSHA and NIOSH's well-settled approach to occupational exposure assessment.

Second, EPA argues that TSCA “uniquely require[s it] to consider information related to the intensity, frequency and duration of exposure.” EPA Br. 77. There is nothing “unique” in this requirement, as duration, intensity, and frequency of exposure are widely recognized as the standard parameters of employee exposure.⁸ Indeed, the crux of this case turns on how EPA defines “employee exposure” for purposes of evaluating risk. In conducting their hazard assessments, OSHA and NIOSH evaluate employee exposure without regard to PPE use, which they consider a “nonrisk factor.” Every OSHA health standard defines “employee exposure” as the exposure “which would occur if the employee were not wearing a respirator.” Labor Br. 26 n.19. Employer measurements of

⁷ See e.g., 89 Fed. Reg. at 102575 (Trichloroethylene) (EPA must consider “potentially exposed [and] susceptible subpopulations” and may not consider costs or other nonrisk factors, requirements that do not apply to OSHA); EPA, “Carbon Tetrachloride Regulation Under [TSCA],” 89 Fed. Reg. 103512, 103516 (Dec. 18, 2024) (same); EPA, “Perchloroethylene Regulation Under [TSCA],” 89 Fed. Reg. 103560, 103564 (Dec. 18, 2024) (same).

⁸ E.g., Centers for Disease Control and Prevention, “NIOSH Practices in Occupational Risk Assessment, Current Intelligence Bulletin No. 69” (2020) at 28, available at <https://www.cdc.gov/niosh/docs/2020-106/pdfs/2020-106revised032020.pdf> (“Exposure indices can be expressed in many ways by using information on three basic dimensions: intensity (e.g., concentration, mass), duration (e.g., hours, days) and frequency (e.g. times per day”).

exposure, taken to comply with OSHA standards, and OSHA compliance measurements are all taken without regard to respirators.⁹ In fact, EPA's recent risk management rules direct covered owners and operators to measure each employee's exposure without regard to respirators. *See, e.g.*, Methylene Chloride, 40 C.F.R. § 751.109(d)(1)(i); Trichlorethylene, *id.* § 751.315(b)(3)(i)(A). *see also*, 89 Fed. Reg. at 103523 (carbon tetrachloride) ("EPA agrees . . . that exposure monitoring should be conducted without regard to respiratory protection to inform engineering control options"); 89 Fed. Reg. at 103575 (perchloroethylene) (same).

EPA attempts to dismiss OSHA and NIOSH's views as expressed only in response to EPA's risk evaluation of methylene chloride, not to the PPE Rule. EPA Br. 69. While it is true that the comments Labor Petitioners cited in their opening brief relate to EPA's risk evaluation of methylene chloride, neither agency confined its comments to the merits of a specific risk evaluation. Instead, both spoke more broadly to whether respirator use should be considered during risk evaluation. Besides, OSHA and NIOSH have raised the same objections in comments on at

⁹ Presumably since employer measurements taken to comply with OSHA regulations routinely measure exposure without regard to respirators, so too do the epidemiology studies on which EPA and other agencies rely to identify chemical hazards.

least two of EPA's other proposed risk evaluations.¹⁰ Both agencies clearly told EPA that taking respirators into account during risk evaluation was wrong.

Neither the Framework Rule nor its preamble acknowledge or distinguish the fact that OSHA and NIOSH do not consider PPE use when conducting risk evaluations. By this omission, EPA not only rejects these agencies' scientific expertise in occupational exposure assessment, it also disregards Congress' explicit instructions that it harmonize its approach with existing occupational health strategies. Congress directed EPA to consult and coordinate with OSHA in administering the Act, 15 U.S.C. § 2608(d), and with NIOSH in prescribing epidemiological studies, *id.* § 2603(b)(2)(A); to include OSHA and NIOSH on its committees to recommend chemicals for priority consideration, *id.* § 2603(e)(2)(A)(ii); to require owners and operators to report on occupational diseases and injuries, *id.* § 2607(c); and to consult with OSHA before prohibiting or restricting new chemical applications that address workplace exposures, *id.* § 2604(f)(5). Indeed, EPA repeatedly claims that its risk management rules strive for consistency with OSHA regulations. 89 Fed. Reg. at 102607 (TCE) (EPA seeks

¹⁰ See AR Ex. 218 at Atts. 1-6. These documents were among the comments on three risk evaluations that Labor Petitioners received from OSHA and NIOSH. EPA has not placed any comments by OSHA and NIOSH in the public record and has actively opposed doing so. So, the comments to which Labor Petitioners refer are the only ones available to them. There is no reason to believe either OSHA or NIOSH have changed their view that it is inappropriate to take respirator use into account when assessing occupational risk.

greater consistency with OSHA on PPE); *Id.* at 21989 (asbestos) (EPA seeks to align its approach to monitoring with OSHA's); *Id.* at 103529 (carbon tetrachloride) (EPA intends PPE programs to be consistent with OSHA's); *Id.*, at 103531 (EPA's worker protection requirements align with OSHA standards to the extent possible). The structure of TSCA, and its emphasis on harmonizing occupational health regulation across relevant agencies, demonstrate that Congress did not intend EPA to invent new approaches to exposure assessment out of whole cloth.

EPA has not “articulate[d] a satisfactory explanation for” its decision to grant itself discretion to consider PPE use in assessing risk. *State Farm*, 463 U.S. at 43. Thus, while treating the views of OSHA and NIOSH as irrelevant, EPA has failed to provide any explanation, in either the preamble to the PPE Rule or in its brief, of how it would consider or evaluate the effectiveness of PPE in assessing risk.¹¹ Nor has EPA explained how considering PPE use is “relevant” or “consistent with the best available science,” as 15 U.S.C. § 2625(h) requires. The sole rationale the Agency has put forward is that there may be instances where PPE

¹¹ EPA could not, for example, simply look at the assigned protection factor (APF) of respirators used by employees to determine whether the PPE is “effective” because appropriate respirator in a given situation is based on the level of protection sought. If going from an exposure of 100 to 10, a respirator with an APF of 10 is fine. If going from an exposure of 100 to 2, it is not. *See* Labor Br. 8–9.

use is “inherent in the performance of an activity.” 89 Fed. Reg. at 37037.

However, EPA have given no example where that may be the case, and other than an atmosphere that is immediately dangerous to life and health, a well-established industrial hygiene concern, we cannot imagine one. *See* Centers for Disease Control and Prevention, NIOSH, “Immediately Dangerous to Life or Health (IDLH) Values, <https://www.cdc.gov/niosh/idlh/default.html> (last accessed Jan. 30, 2025). Moreover, the very suggestion demonstrates the folly of utilizing information about PPE use to discount employee exposure: If there were a condition of use in which toxic exposures were so hazardous that employees could not perform the work without PPE, discounting the risk based on information about the PPE’s purported effectiveness would lead to the counter-intuitive conclusion that this ultra-hazardous condition did *not* present an unreasonable risk. That simply cannot be what Congress intended.

By adopting this rule, EPA is claiming the right to rely on “factors which Congress has not intended it to consider.” *State Farm*, 463 U.S. at 43. Moreover, as its decision regarding how to evaluate workplace exposures runs contrary to the advice provided by OSHA and NIOSH—the agencies with decades of experience—it cannot be “ascribed to . . . the product of agency expertise.” *Id.* The Agency’s action is therefore quintessentially arbitrary.

IV. TSCA Bars EPA from Considering PPE, a Nonrisk Factor, During Risk Evaluation

TSCA instructs EPA, “in conducting a risk evaluation . . . not [to] consider costs or other nonrisk factors.” 15 U.S.C. § 2605(b)(4)(F)(iii). PPE is a risk management tool, and thus, a “nonrisk” factor, which TSCA precludes EPA from taking into account in conducting its risk assessments. OSHA and NIOSH have both advised EPA that PPE is a means of controlling exposures, albeit the least effective means and thus, least favored on the hierarchy of controls. We do not suggest EPA ignore information on PPE use. EPA can consider information regarding the effectiveness of PPE when assessing the “cost” and “cost-effectiveness” of risk management options under 15 U.S.C. § 2605(c)(2)(A)((iv).

In fact, EPA also routinely describes respirators “as a means of compliance.” *See* EPA, “A Compliance Guide for the Workplace Chemical Protection Program Under the Toxic Substances Control Act,” (Jan. 2025), at 7, *available at* <https://www.epa.gov/system/files/documents/2025-01/general-wcpp-guide.pdf> (risk management compliance guide describing respirators “as a means of compliance”); EPA, “A Guide to Complying with the 2024 Trichloroethylene (TCE) Regulation under the Toxic Substances Control Act (TSCA) (RIN 2070-AK83),” (Jan. 2025), at 24-25, *available at* https://www.epa.gov/system/files/documents/2025-01/tce-compliance-guide_0.pdf.

(trichloroethylene risk management guide describing respirators as an “exposure control measure”).

Other than repeating the claim that it is required to consider “all reasonably available information,” EPA has cited nothing, and in fact, has failed to articulate any theory, to support its view that PPE effectiveness is *not* a “nonrisk” factor for purposes of risk evaluation. It has not pointed to a single occupational risk evaluation that has discounted airborne exposure measurements based on either assumed or actual PPE use. The two expert agencies with experience in occupational exposure assessment dismissed EPA’s approach as wrong, but EPA disregarded their views. The PPE rule therefore must be set aside as “not in accordance with law.” 5 U.S.C. § 706(2)(A).

V. No Deference Is Due EPA’s Interpretation of Section 2625(k)

The question before the Court is one of statutory interpretation. TSCA instructs EPA to assess risks without regard to “nonrisk factors,” 15 U.S.C. § 2605(b)(4)(F)(iii), and to do so using the best available scientific information, in a manner that is relevant and consistent with its intended use, *id.* § 2625(h), (i). EPA contends that all of this is trumped by § 2625(k)’s instruction that it consider all “reasonably available” information.

When interpreting statutory terms, “[c]ourts must exercise their independent judgment in deciding whether an agency has acted within its statutory authority.”

EPA Br. at 18 (quoting *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 412 (2024)). While EPA’s interpretation of TSCA may, in some respects, “help inform” the Court’s inquiry, *Loper Bright*, 603 U.S. at 413, here the scientific and technical expertise lies with OSHA and NIOSH, rather than EPA. *Huntsman Petrochem.*, 114 F.4th at 735 (Court grants “extreme degree of deference” to an agency’s “evaluation of scientific data within its area of expertise”). Nothing in TSCA differentiates EPA’s obligations in conducting risk evaluations from OSHA and NIOSH’s obligation to determine “significant risk.” By its own admission, EPA’s prior involvement in occupational risk evaluation has been sparse. EPA Br. 7. By contrast, OSHA and NIOSH have been evaluating risk for decades, consistently taking the position that “employee exposure is measured without regard to respirators because they are a risk management tool.” AR Ex. 218 at Att. 1-6. We urge this Court to credit those agencies’ “body of experience” and the consistency of their “informed judgment” in finding that EPA has acted arbitrarily in adopting the PPE Rule. *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944).

VI. Labor Petitioners’ Claims Are Ripe

Contrary to EPA’s characterization, the Labor Petitioners are not arguing that the Agency *should* not consider PPE use in assessing risk. EPA Br. 59. Our position is that TSCA *prohibits* the Agency from considering PPE use in assessing risk. In short, given Congress’ direction that EPA cannot consider “nonrisk” factors in

assessing risk, and its demand that EPA base its risk evaluations on the best available, relevant and appropriate science, there are *no* circumstances under which the first sentence of this Rule—either by its own terms or as described by EPA—can validly be applied. *Ass’n of Private Sector Colls. v. Duncan*, 681 F.3d 427, 442 (D.C. Cir. 2012).

Thus, Labor Petitioners’ challenge to the PPE Rule satisfies both the constitutional and prudential ripeness requirements. The Article III “requirement for ripeness is injury in fact,” that is, “whether the requisite injury is in sharp enough focus and the adverseness of the parties concrete enough to permit a court to decide a real controversy.” *DKT Memorial Fund Ltd. v. Agency for Intern. Dev.*, 887 F. 2d 275, 297 (D.C. Cir. 1989) (internal citation and quotation marks omitted). Here, the injury—EPA’s adoption of a clearly unlawful rule that the Agency definitively intends to apply in determining whether toxic substances pose unreasonable risks to Labor Petitioners’ members—is concrete, and the fully-briefed positions of the parties present a real controversy.

This case similarly satisfies the prudential ripeness doctrine, which evaluates “the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration.” *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967). The issue here is “fit[. . .]for judicial decision.” As in *Abbott Labs.*, this is

a final rule, *id.*; and it involves a purely legal question: whether TSCA permits EPA to consider respirator use in evaluating risk.

Withholding decision would, moreover, create hardship for the parties. Congress amended TSCA in 2016 to push EPA to deal quickly and deliberately with toxic substances, after years of inaction. The amended law demands that EPA prioritize chemicals for evaluation, propose and complete risk assessments, and where the Agency finds unreasonable risk, propose and finalize risk management rules, all with opportunities for public comment and all on tight time frames. 15 U.S.C. § 2605(b)(4)(G) (setting deadlines for risk evaluation); *id.* § 2605(c)(1) (setting deadlines for risk management); *id.* § 2619(a)(2) (allowing citizen suits against EPA for failing to comply with the deadlines in TSCA). If EPA determines, after reducing measured employee exposure by the supposed efficacy of PPE, that guided by its Framework Rule, a chemical does not pose an unreasonable risk, individual challenges to each chemical risk evaluation will be required. If EPA finds unreasonable risk, judicial review must wait until the Agency promulgates its final risk management rule. *Id.* § 2618. Waiting until the EPA completes an entire risk evaluation and risk management process before evaluating the legality of the PPE Rule, and doing so one chemical at a time, would throw a monkey wrench into this entire system, potentially requiring the Agency to start the process again, thereby undermining congressional intent and creating hardships for the Agency,

for the parties to these public processes, and most critically, for the workers who remain subject to the unreasonable risks posed by exposure to toxic chemicals.

When reviewing EPA's earlier version of the Framework Rule, the Ninth Circuit held that when an agency binds itself to a particular course, claims that the course is wrong are ripe. *Safer Chemicals, Healthy Families v. EPA*, 947 F.3d 397, 421 (9th Cir. 2019). Here, EPA has said it *must*—not *may*—consider evidence we argue it cannot. EPA Br. 65 (“it would be unreasonable, and in fact unlawful, for EPA to fail to consider reasonably available exposure information regarding the use and effectiveness of personal protective equipment in occupational settings”). That makes Labor Petitioners' claims ripe.

CONCLUSION

In adopting a Rule that grants it unbridled discretion to take PPE use and efficacy into account in evaluating risk, EPA is not only claiming the right to “rel[y] on factors which Congress has not intended it to consider,” *State Farm*, 463 U.S. at 43, it is relying on factors Congress expressly directed it *not* to consider. Moreover, in promulgating this Rule, EPA has misconstrued the statute, “entirely fail[ed] to consider . . . important aspect[s] of the problem” presented to it by more experienced agencies, “offered an explanation of its decision that runs counter to the evidence before [it], and is so implausible that it [cannot] be ascribed to a difference in view or the product of agency expertise.” *Id.* Because the Rule is

arbitrary, capricious and contrary to the law, we respectfully submit that it the first sentence of 40 C.F.R. § 702.39(f)(2) should be stricken from the Framework Regulation.¹²

Respectfully submitted,

/s/ Randy S. Rabinowitz

Randy S. Rabinowitz

Victoria L. Bor

Occupational Safety and Health Law
Project, LLC

P.O. Box 3769

Washington, D.C. 20027

Counsel for Labor Petitioners

¹² The first sentence of § 702.39(f)(2) is easily severable from the rest of the Framework Rule. We therefore respectfully submit that vacatur is inappropriate, and request that the Court not vacate the entire regulation, but simply hold this provision invalid and order EPA to strike it from the Framework Rule.

STATUTORY APPENDIX

15 U.S.C. § 2625 - Administration

(h) Scientific standards

In carrying out sections 2603, 2604, and 2605 of this title, to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science, and shall consider as applicable—

- (1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;
- (2) the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;
- (3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;
- (4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and
- (5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models.

(i) Weight of scientific evidence

The Administrator shall make decisions under sections 2603, 2604, and 2605 of this title based on the weight of the scientific evidence.

(k) Reasonably available information

In carrying out sections 2603, 2604, and 2605 of this title, the Administrator shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator.

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because the brief uses a proportionally spaced typeface and contains 5134 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in 14-point typeface using Time New Roman font.

/s/ Victoria L. Bor
Victoria L. Bor

Counsel for Labor Petitioners

February 3, 2025

CERTIFICATE OF SERVICE

I hereby certify that I e-filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the D.C. Circuit by using the appellate CM/ECF system on February 3, 2025.

Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

Dated: February 3, 2025
Washington, D.C.

/s/ Victoria L. Bor
Victoria L. Bor

Counsel for Labor Petitioners